COMMITTEE REPORT

MADAM PRESIDENT:

The Senate Committee on Health and Provider Services, to which was referred House Bill No. 1325, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Delete the title and insert the following:

A BILL FOR AN ACT to amend the Indiana Code concerning human services.

Page 1, between the enacting clause and line 1, begin a new paragraph and insert:

"SECTION 1. IC 12-15-5-5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 5. **(a) The office may provide a prescription drug benefit to a Medicaid recipient in the Medicaid risk based managed care program.**

(b) If the office provides a prescription drug benefit to a Medicaid recipient in the Medicaid risk based managed care program:

(1) the office shall develop a procedure and provide the recipient's risk based managed care provider with information concerning the recipient's prescription drug utilization for the risk based managed care provider's case management program; and

(2) the provisions of IC 12-15-35.5 apply.

(c) If the office does not provide a prescription drug benefit to a Medicaid recipient in the Medicaid risk based managed care program, a Medicaid managed care organization ~~that provides~~ **shall**

provide coverage and reimbursement for outpatient single source legend drugs ~~is~~ subject to IC 12-15-35-46, ~~and~~ IC 12-15-35-47, **and IC 12-15-35.5.**

SECTION 2. IC 12-15-12-4.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.5. A managed care provider's contract or provider agreement with the office may include a prescription drug program, subject to IC 12-15-5-5, IC 12-15-35, and IC 12-15-35.5.**

SECTION 3. IC 12-15-35-28, AS AMENDED BY P.L.28-2004, SECTION 104, AND AS AMENDED BY P.L.97-2004, SECTION 51, IS CORRECTED AND AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 28. (a) The board has the following duties:

(1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.

(2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software programs to be used by the pharmacist for prospective DUR and recommendations concerning the provisions of the contractual agreement between the state and any other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.

(3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.

(4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.

(5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council

by December 1 of each year. The report *issued* to the legislative council must be in an electronic format under IC 5-14-6.

(6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:

(A) The Indiana board of pharmacy.

(B) The medical licensing board of Indiana.

(C) The SURS staff.

(7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.

(8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under ~~410 IAC 16.2-3-8~~ **410 IAC 16.2-3.1** and 42 CFR 483.60.

(11) The research, development, and approval of a preferred drug

list for:

(A) Medicaid's fee for service program;

(B) Medicaid's primary care case management program; ~~and~~

(C) Medicaid's risk based managed care program, if the office provides a prescription drug benefit and subject to IC 12-15-5; and

~~(C)~~ **(D)** ~~the primary care case management component of~~ the children's health insurance program under IC 12-17.6;

in consultation with the therapeutics committee.

(12) The approval of the review and maintenance of the preferred drug list at least two (2) times per year.

(13) The preparation and submission of a report concerning the preferred drug list at least two (2) times per year to the select joint commission on Medicaid oversight established by IC 2-5-26-3.

(14) The collection of data reflecting prescribing patterns related to treatment of children diagnosed with attention deficit disorder or attention deficit hyperactivity disorder.

(15) Advising the Indiana comprehensive health insurance association established by IC 27-8-10-2.1 concerning implementation of chronic disease management and pharmaceutical management programs under IC 27-8-10-3.5.

(b) The board shall use the clinical expertise of the therapeutics committee in developing a preferred drug list. The board shall also consider expert testimony in the development of a preferred drug list.

(c) In researching and developing a preferred drug list under subsection (a)(11), the board shall do the following:

(1) Use literature abstracting technology.

(2) Use commonly accepted guidance principles of disease management.

(3) Develop therapeutic classifications for the preferred drug list.

(4) Give primary consideration to the clinical efficacy or appropriateness of a particular drug in treating a specific medical condition.

(5) Include in any cost effectiveness considerations the cost implications of other components of the state's Medicaid program and other state funded programs.

(d) Prior authorization is required for coverage under a program described in subsection (a)(11) of a drug that is not included on the

preferred drug list.

(e) The board shall determine whether to include a single source covered outpatient drug that is newly approved by the federal Food and Drug Administration on the preferred drug list not later than sixty (60) days after the date on which the manufacturer notifies the board in writing of the drug's approval. However, if the board determines that there is inadequate information about the drug available to the board to make a determination, the board may have an additional sixty (60) days to make a determination from the date that the board receives adequate information to perform the board's review. Prior authorization may not be automatically required for a single source drug that is newly approved by the federal Food and Drug Administration, and that is:

(1) in a therapeutic classification:

(A) that has not been reviewed by the board; and

(B) for which prior authorization is not required; or

(2) the sole drug in a new therapeutic classification that has not been reviewed by the board.

(f) The board may not exclude a drug from the preferred drug list based solely on price.

(g) The following requirements apply to a preferred drug list developed under subsection (a)(11):

(1) Except as provided by IC 12-15-35.5-3(b) and IC 12-15-35.5-3(c), the office or the board may require prior authorization for a drug that is included on the preferred drug list under the following circumstances:

(A) To override a prospective drug utilization review alert.

(B) To permit reimbursement for a medically necessary brand name drug that is subject to generic substitution under IC 16-42-22-10.

(C) To prevent fraud, abuse, waste, overutilization, or inappropriate utilization.

(D) To permit implementation of a disease management program.

(E) To implement other initiatives permitted by state or federal law.

(2) All drugs described in IC 12-15-35.5-3(b) must be included on the preferred drug list.

(3) The office may add a drug that has been approved by the

federal Food and Drug Administration to the preferred drug list without prior approval from the board.

(4) The board may add a drug that has been approved by the federal Food and Drug Administration to the preferred drug list.

(h) At least two (2) times each year, the board shall provide a report to the select joint commission on Medicaid oversight established by IC 2-5-26-3. The report must contain the following information:

(1) The cost of administering the preferred drug list.

(2) Any increase in Medicaid physician, laboratory, or hospital costs or in other state funded programs as a result of the preferred drug list.

(3) The impact of the preferred drug list on the ability of a Medicaid recipient to obtain prescription drugs.

(4) The number of times prior authorization was requested, and the number of times prior authorization was:

(A) approved; and

(B) disapproved.

(i) The board shall provide the first report required under subsection (h) not later than six (6) months after the board submits an initial preferred drug list to the office.

SECTION 4. IC 12-15-35-45 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 45. (a) The chairman of the board, subject to the approval of the board members, may appoint an advisory committee to make recommendations to the board on the development of a Medicaid outpatient drug formulary.

(b) If the office decides to establish a Medicaid outpatient drug formulary, the formulary shall be developed by the board.

(c) A formulary, **preferred drug list, or prescription drug benefit** used by a Medicaid managed care organization is subject to **IC 12-15-5-5, IC 12-15-35.5, and** sections 46 and 47 of this chapter.

SECTION 5. IC 12-15-35.5-1 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 1. ~~(a) Except as provided in subsection (b),~~ This chapter applies to:

(1) the Medicaid program under this article; and

(2) the children's health insurance program under IC 12-17.6.

~~(b) This chapter does not apply to a formulary or prior authorization program operated by a managed care organization under a program described in subsection (a).~~

SECTION 6. IC 12-15-35.5-3 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 3. (a) Except as provided in subsection (b), the office may establish prior authorization requirements for drugs covered under a program described in ~~section 1(a)~~ **section 1** of this chapter.

(b) The office may not require prior authorization for the following single source or brand name multisource drugs:

(1) A drug that is classified as an antianxiety, antidepressant, or antipsychotic central nervous system drug in the most recent publication of Drug Facts and Comparisons (published by the Facts and Comparisons Division of J.B. Lippincott Company).

(2) A drug that, according to:

(A) the American Psychiatric Press Textbook of Psychopharmacy;

(B) Current Clinical Strategies for Psychiatry;

(C) Drug Facts and Comparisons; or

(D) a publication with a focus and content similar to the publications described in clauses (A) through (C);

is a cross-indicated drug for a central nervous system drug classification described in subdivision (1).

(3) A drug that is:

(A) classified in a central nervous system drug category or classification (according to Drug Facts and Comparisons) that is created after the effective date of this chapter; and

(B) prescribed for the treatment of a mental illness (as defined in the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

(c) Except as provided under section 7 of this chapter, a recipient enrolled in a program described in ~~section 1(a)~~ **section 1** of this chapter shall have unrestricted access to a drug described in subsection (b).

SECTION 7. IC 12-15-35.5-7 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 7. (a) Subject to ~~subsection~~ **subsections** (b) **and (c),** the office may place limits on quantities dispensed or the frequency of refills for any covered drug for the purpose of:

(1) preventing fraud, abuse, **or** waste;

(2) preventing overutilization, ~~or~~ inappropriate utilization, **or**

inappropriate prescription practices that are contrary to:

(A) clinical quality and patient safety; and

(B) accepted clinical practice for the diagnosis and treatment of mental illness; or

~~(2)~~ **(3)** implementing a disease management program.

(b) Before implementing a limit described in subsection (a), the office shall:

(1) consider quality of care and the best interests of Medicaid recipients;

(2) seek the advice of the drug utilization review board, established by IC 12-15-35-19, at a public meeting of the board; and

(3) publish a provider bulletin that complies with the requirements of IC 12-15-13-6.

(c) Subject to subsection (d), the board may establish and the office may implement a restriction on a drug described in section 3(b) of this chapter if:

(1) the board determines that data provided by the office indicates that a situation described in IC 12-15-35-28(a)(8)(A) through IC 12-15-35-28(a)(8)(K) requires an intervention to:

(A) prevent fraud, abuse, **or** waste;

(B) prevent overutilization, ~~or~~ inappropriate utilization, or **inappropriate prescription practices that are contrary to:**

(i) clinical quality and patient safety; and

(ii) accepted clinical practice for the diagnosis and treatment of mental illness; or

~~(B)~~ **(C)** implement a disease management program; **and**

(2) the board approves and the office implements an educational intervention program for providers to address the situation. ~~and~~

~~(3) at least six (6) months after the implementation of the educational intervention program described in subdivision (2), the board determines that the situation requires further action.~~

(d) A restriction established under subsection (c) for any drug described in section 3(b) of this chapter:

(1) must comply with the procedures described in IC 12-15-35-35;

(2) may include requiring a recipient to be assigned to one (1) practitioner and one (1) pharmacy provider for purposes of receiving mental health medications;

(3) may not lessen the quality of care; and

(4) must be in the best interest of Medicaid recipients.

(e) Implementation of a restriction established under subsection (c) must provide ~~that only the prescribing practitioner may authorize an~~ **for the dispensing of a temporary supply of the drug for a prescription not to exceed seven (7) business days, if additional time is required to review the request for** override of the restriction. **This subsection does not apply if the federal Food and Drug Administration has issued a boxed warning under 21 CFR 201.57(e) that applies to the drug and is applicable to the patient.**

(f) Before implementing a restriction established under subsection (c), the office shall:

(1) seek the advice of the mental health quality advisory committee until June 30, 2007; and

(2) publish a provider bulletin that complies with the requirements of IC 12-15-13-6.

(g) Subsections (c) through (f):

(1) apply only to drugs described in section 3(b) of this chapter; and

(2) do not apply to a restriction on a drug described in section 3(b) of this chapter that was approved by the board and implemented by the office before April 1, 2003.

SECTION 8. [EFFECTIVE JULY 1, 2005] **(a) As used in this SECTION, "committee" refers to the mental health quality advisory committee established in subsection (c).**

(b) As used in this SECTION, "office" refers to the office of Medicaid policy and planning established by IC 12-8-6-1.

(c) The mental health quality advisory committee is established. The committee consists of the following members:

(1) The director of the office or the director's designee, who shall serve as chairperson of the committee.

(2) The director of the division of mental health and addiction or the director's designee.

(3) A representative of a statewide mental health advocacy organization.

(4) A representative of a statewide mental health provider organization.

(5) A representative from a managed care organization that

participates in the state's Medicaid program.

(6) A member with expertise in psychiatric research representing an academic institution.

(7) A pharmacist licensed under IC 25-26.

The governor shall make the appointments under subdivisions (3) through (7) and fill any vacancy on the committee.

(d) The office shall staff the committee. The expenses of the committee shall be paid by the office.

(e) Each member of the committee who is not a state employee is entitled to the minimum salary per diem provided by IC 4-10-11-2.1(b). The member is also entitled to reimbursement for traveling expenses as provided under IC 4-13-1-4 and other expenses actually incurred in connection with the member's duties as provided in the state policies and procedures established by the Indiana department of administration and approved by the budget agency.

(f) Each member of the committee who is a state employee is entitled to reimbursement for traveling expenses as provided under IC 4-13-1-4 and other expenses actually incurred in connection with the member's duties as provided in the state policies and procedures established by the Indiana department of administration and approved by the budget agency.

(g) The affirmative votes of a majority of the voting members appointed to the committee are required by the committee to take action on any measure, including a final report.

(h) The committee shall advise the office and make recommendations concerning the implementation of IC 12-15-35.5-7(c) and consider the following:

(1) Peer reviewed medical literature.

(2) Observational studies.

(3) Health economic studies.

(4) Input from physicians and patients.

(5) Any other information determined by the committee to be appropriate.

(i) The office shall report recommendations made by the committee to the drug utilization review board established by IC 12-15-35-19.

(j) The office shall report the following information to the select

joint commission on Medicaid oversight established by IC 2-5-26-3:

(1) The committee's advice and recommendations made under this SECTION.

(2) The number of instances that occur under the restriction described in IC 12-15-35.5-7(c) and the outcome of each occurrence.

(3) The transition of the aged, blind, and disabled population to the risk based managed care program. This information shall also be reported to the health finance commission established by IC 2-5-23-3.

(4) Any decision by the office to change the health care delivery system in which Medicaid is provided to recipients.

(k) This SECTION expires June 30, 2007.

SECTION 9. [EFFECTIVE JULY 1, 2005] **(a) The following are void:**

(1) 405 IAC 5-24-8.5.

(2) 405 IAC 5-24-8.6.

(3) 405 IAC 5-24-11.

(b) The publisher of the Indiana Administrative Code and the Indiana Register shall remove these provisions from the Indiana Administrative Code.

(c) This SECTION expires December 31, 2006.

SECTION 10. [EFFECTIVE JULY 1, 2005] **(a) As used in this SECTION, "managed care provider" refers to a managed care organization that has entered into a contract with the office to provide services under Medicaid's risk based managed care program.**

(b) As used in this SECTION, "office" refers to the office of Medicaid policy and planning established by IC 12-8-6-1.

(c) IC 12-15-12-4.5, as added by this act, applies to a provider agreement or contract entered into, amended, or renewed after

June 30, 2005, between the office and a managed care provider.

(d) This SECTION expires December 31, 2010.".

Renumber all SECTIONS consecutively.

(Reference is to HB 1325 as printed January 25, 2005.)

and when so amended that said bill do pass.

Committee Vote: Yeas 9, Nays 0.

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Miller **Chairperson**